

Appln. No. 09/155,676

Amdt. dated December 14, 2005

Reply to Office action of June 14, 2005

REMARKS

Claims 13-16, 20-22, 30, 43-47, 49, 50, 53-60, 62-71, 73-75 and 77-79 presently appear in this case. Claim 62 has been allowed, and claims 66 and 68 have been indicated to be allowable if rewritten in independent form. The remaining claims have been rejected. The official action of June 14, 2005, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to cDNA sequences that encode polypeptides that bind to TRAF2 and inhibit or increase activity of NF- κ B as well as the polypeptides encoded by those DNA sequences. Preferably, the polypeptide is NIK. The invention also relates to antibodies, methods of identification and screening, and anti-sense DNA.

It is noted that the examiner has approved the proposed drawing corrections and accepted the drawings filed on April 19, 2000. It is further noted that the examiner has acknowledged applicants' claim for priority and receipt of all of the certified copies of the priority documents. Furthermore, it is noted that the examiner has approved the substitute specification submitted on September 10, 2001, as well as the sequence listing submitted on April 4, 2005.

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Claims 20, 22, 50, 53-59, 63, 65, 69-71, 73-75 and 77-79 have been rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. The examiner states that the scope of the claims' subject matter encompasses polypeptides and nucleic acid sequences that are a product of nature.

The claims have now been amended so as to avoid this rejection. The polypeptide claims all specify that they are isolated polypeptides. The antibody claims have been amended to specify that the claims are directed to "an isolated molecule comprising an antibody, active fragment of the antibody" This does not read on a product of nature. The DNA claims have been amended so as to be directed to a DNA molecule consisting of an isolated DNA sequence encoding a specified polypeptide sequence or consisting of a recombinant vector comprising said DNA sequence. Neither alternative can read on a product of nature. Accordingly, this new rejection has now been obviated.

Claims 30, 45, 47-49 and 64 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. With respect to claim 30, the examiner states that the claim is incomplete because there is no actual step recited in the method for isolating or identifying a polypeptide.

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Claim 30 has now been amended to insert the step suggested by the examiner. Accordingly, it is believed that this rejection has now been obviated with respect to claim 30.

With respect to claim 45, the examiner states that the claim recites human TRAF2, having the amino acid residues 222-501 of TRAF2 but without specifying a particular sequence of TRAF2.

In order to avoid this rejection, the specification has now been amended to insert in paragraph [0176] the known sequence for TRAF2 as disclosed in the prior art. Insertion of this SEQ ID NO is not new matter as the sequence of this known protein was acknowledged as being known at the time the present application was filed. It is the same sequence that appears in GenBank record NP 066961, a copy of which is attached hereto. Accordingly, specifying this sequence now merely makes explicit that which had been implicit in the specification as filed. Claim 45 has now been amended to also refer to this same SEQ ID NO:23, thus avoiding the indefiniteness previously noted by the examiner.

Applicants have added into the present specification a new paper copy Sequence Listing section according to 37 C.F.R. §1.821(c) as new pages 1-54. This new

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paper copy includes sequence 23. Furthermore, attached hereto is a 3 1/2" disk containing the "Sequence Listing" in computer readable form in accordance with 37 C.F.R.

§1.821(e). The paper and computer readable form are attached hereto as Appendix A.

The following statement is provided to meet the requirements of 37 C.F.R. §1.821(f) and 1.821(g) §1.825(a) and 1.825(b).

I hereby state, in accordance with 37 C.F.R. §1.825(a), that the amendments included in the substitute sheets of the sequence listing are believed to be supported in the application as filed and that the substitute sheets of the sequence listing are not believed to include new matter.

I hereby further state, in accordance with 37 C.F.R. §1.825(b), that the attached copy of the computer readable form is the same as the attached substitute paper copy of the sequence listing.

Under U.S. rules, each sequence must be classified in <213> as an "Artificial Sequence", a sequence of "Unknown" origin, or a sequence originating in a particular organism, identified by its scientific name.

Neither the rules nor the MPEP clarify the nature of the relationship which must exist between a listed

sequence and an organism for that organism to be identified as the origin of the sequence under <213>.

Hence, counsel may choose to identify a listed sequence as associated with a particular organism even though that sequence does not occur in nature by itself in that organism (it may be, e.g., an epitopic fragment of a naturally occurring protein, or a cDNA of a naturally occurring mRNA, or even a substitution mutant of a naturally occurring sequence). Hence, the identification of an organism in <213> should not be construed as an admission that the sequence *per se* occurs in nature in said organism.

Similarly, designation of a sequence as "artificial" should not be construed as a representation that the sequence has no association with any organism. For example, a primer or probe may be designated as "artificial" even though it is necessarily complementary to some target sequence, which may occur in nature. Or an "artificial" sequence may be a substitution mutant of a natural sequence, or a chimera of two or more natural sequences, or a cDNA (i.e., intron-free sequence) corresponding to an intron-containing gene, or otherwise a fragment of a natural sequence.

The examiner should be able to judge the relationship of the enumerated sequences to natural

sequences by giving full consideration to the specification, the art cited therein, any further art cited in an IDS, and the results of his or her sequence search against a database containing known natural sequences.

Accordingly, reconsideration and withdrawal of this rejection insofar as it refers to claim 45 are respectfully urged.

As to claims 47-49 and 64, the examiner states that these claims recite "the cellular activity which is changed or mediated by" the polypeptide of claims 53, 62, 69 and/or NIK. The examiner states that there is insufficient basis for this limitation in these claims such that the ordinary skilled artisan would be unable to ascertain which "cellular activity" applicants are referring to in order to avoid infringement. This part of the rejection is respectfully traversed.

Claims 47-49 and 64 are all simply screening claims. It is not important which "cellular activity" of NIK is being referred to as an inhibition or increase of any of the cellular activities of NIK would be of interest. Nevertheless, in order to obviate this rejection, claims 47, 49 and 64 have now been amended to delete reference to cellular activity and only look for molecules capable of binding to the target polypeptide. Screening for such

binding proteins has sufficient utility even if just for affinity chromatography. Thus, it is not necessary to screen for cellular activity, and this rejection has now been obviated. Claim 48 has been deleted, without prejudice, as being a substantial duplicate of claim 47 as amended.

Claims 13-16, 20-22, 43-45, 49, 50, 54, 55, 59, 60, 63, 69 and 77-79 remain rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement for the reasons of record. The examiner specifically objects to the reference to fragments. This rejection is respectfully traversed.

First, applicants hereby incorporate by reference all arguments previously made with respect to this rejection. However, in an attempt to obviate this rejection, the claims have now been amended to specify that the polypeptide "consists of" the amino acid sequence of the fragment or that the DNA sequence "consists of" a fragment of the sequence that encodes the polypeptide. Thus, the claims cannot be interpreted as reading on a completely unrelated sequence having the specified properties that has only one or two amino acids from the specified polypeptide of (a) of the claim. Indeed, it is the fragment that must have the activity, not the polypeptide that comprises the fragment.

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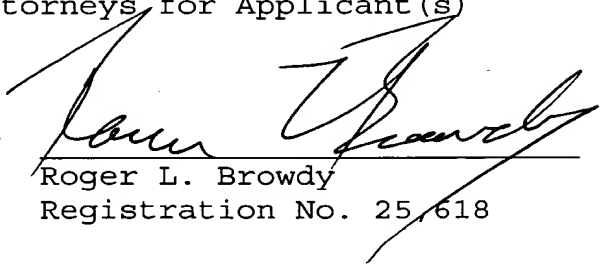
The scope of the fragment part of the claim is now very reasonable, as requiring the polypeptide to consist of a portion of the entire protein, which portion has the specified activity. It is believed that these changes render the present rejection moot. Reconsideration and withdrawal thereof are therefore respectfully urged.

It is submitted that all the claims now present in the case fully comply with 35 U.S.C. §112 and clearly define over the references of record. Reconsideration and allowance are hereby earnestly solicited.

Respectfully submitted,

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Appendix A

Paper Copy of Sequence Listing and Disk